No. 92-800

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES, *et al.*,

and

WILLIAM K. REILLY, Administrator of the Environmental Protection Agency, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Ninth Circuit correctly held that the Environmental Protection Agency violated section 409 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 348, by refusing to revoke regulations permitting the use of benomyl, mancozeb, phosmet and trifluralin as food additives despite having determined that these substances induce cancer?

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BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION *

STATEMENT OF THE CASE

Section 409 of the Federal Food, Drug and Cosmetic Act ("FFDCA") contains a proviso, known as the "Delaney clause," that explicitly mandates that "no

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* The private party respondents are the petitioners in the court below (Kathleen E. Les, Frances Les Thomas, Manuel Jesus Perez Morales, David R. Perez, and Manuel R. Perez) and petitioner-intervenors below (American Federation of Labor and Congress of Industrial Organizations, Natural Resources Defense Council, Inc., and Public Citizen).

[food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal . . . ." 21 U.S.C. § 348(c)(3). For over 25 years, Congress, the courts and the agencies responsible for implementing this clause—and the two parallel clauses regulating animal drugs and color additives (*id.*, §§ 360b(d)(1)(H), 376(b)(5)(B))—have read the statutory language as imposing an *absolute* ban on the use of carcinogens in food additives, color additives or animal drugs.

The Delaney clause's express prohibition on the use of any cancer-inducing food additive reflects Congress' judgment that safe thresholds cannot be established for carcinogenic substances. Over the years, opponents of this "zero-risk" policy have attacked the Delaney clause as overly restrictive, claiming that science is able to set acceptable risk levels. Until recently, however, all parties to the debate have accepted the fundamental premise that any alteration of this policy would require congressional action.

In 1985, the Food and Drug Administration (FDA), embarked upon a short-lived attempt to create a *de minimis* exception to the color additive Delaney clause. That attempt was struck down by the United States Court of Appeals for the District of Columbia Circuit in *Public Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988). The D.C. Circuit affirmed that such an agency-created exception is inconsistent with the statutory language and congressional intent, and that FDA's policy concerns were properly addressed to Congress. In the years since the *Public Citizen* decision, FDA, which has authority not only over color additives but also over all food additives other than pesticides, has made no further attempt to engraft a *de minimis* exception onto any of the three Delaney clause provisions.

Against this background, "[t]he proceedings in this case had their genesis in October 1988 when . . . . [the

Environmental Protection Agency] announced a new interpretation of the Delaney clause . . . ." Pet. App. 5a. EPA declared—thirty years after the clause was enacted and one year after the *Public Citizen* decision was rendered—that food additives containing pesticides that concentrate in processed foods above the levels permitted on raw foods and that had been found to induce cancer would now be permitted "so long as the particular substances posed only a 'de minimis' risk of actually causing cancer." *Id.* (quoting Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,110 (Oct. 19, 1988)).

At the same time, EPA announced that the Agency had determined that certain pesticide chemicals, including the four at issue here—for which EPA had previously issued regulations under the Delaney clause permitting their use as food additives on the ground that the chemicals were *not* carcinogenic—did in fact induce cancer within the meaning of the Delaney clause. *Id.* at 3a (citing 53 Fed. Reg. at 41,119).

Respondents petitioned EPA to revoke the regulations permitting the use of seven cancer-causing substances as food additives. In February, 1991, EPA refused to revoke the regulations for four of these substances, despite its own conclusion that each had been found to induce cancer. Final Order Responding to Objections to EPA's Response to Petition Requesting Revocation of Food Additive Regulations ("Final Order"), 56 Fed. Reg. 7750 (1991), *reprinted at* Pet. App. 12a. Respondents sought review of EPA's Final Order in the United States Court of Appeals for the Ninth Circuit.

The Ninth Circuit set aside EPA's order, finding that:

> the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit *all* [food] additives that are carcinogens, regardless of risk involved.

Pet. App. 2a-3a (emphasis added). The Ninth Circuit subsequently denied EPA's petition for rehearing. On December 16, 1992, EPA informed the Ninth Circuit that it would not be seeking certiorari.

REASONS FOR DENYING THE WRIT

The Ninth Circuit's decision is entirely sound, is consistent with this Court's precedent regarding judicial review of agency action and is not in conflict with the decision of any other circuit. Accordingly, there is no basis for this Court's review, and the *certiorari* petition filed by the National Agricultural Chemicals Association (NACA) should be denied.[1]

1. NACA argues that the Ninth Circuit's "rigid adherence to the literal language of the Delaney clause[] squarely conflicts with the *de minimis* principle of statutory construction repeatedly recognized by this Court." Pet. at 15. According to NACA, there is a general principle that no matter what a statute says, agencies *always* have inherent authority to refrain from regulation of *de minimis* risks. *See* Pet. at 15. There is no such general principle.

In *Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S.Ct. 2447 (1992), on which petitioner relies, this Court explained that the *de minimis* principle applies "*absent contrary indication.*" *Id.* at 2458 (emphasis added). Similarly, in *Public Citizen*, the D.C. Circuit, in finding that the color additive Delaney clause prohibited FDA from creating a *de minimis* exception, explained that "the doctrine obviously is not available to thwart a statutory command . . . ." 831 F.2d at 1113.

Here, the Ninth Circuit found such "contrary indication" to a *de minimis* exception in the "clear and mandatory language" of the statute; the "legislative history [which] reflects that Congress intended th[at] very

[1] We note that the government has determined *not* to file a *certiorari* petition seeking review of the decision below and, instead, has filed a brief opposing NACA's *certiorari* petition.

rigidity"; the contemporaneous agency interpretation which "interpreted the clause as removing all agency discretion regarding carcinogens"; and "Congress[']repeated[] ratifi[cation of] a strict interpretation of the Delaney clause." Pet. App. 6a, 8a-9a.[2]

2. NACA argues further that the Ninth Circuit should have deferred to EPA's interpretation of the Delaney clause. But, as this Court has explained, in interpreting a statute, the first question is "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). Where the intent of Congress is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842. That portion of the *Chevron* rule governs here.

The Delaney clause clearly states that "*no* additive shall be deemed to be safe if it is found to induce cancer . . . ." 21 U.S.C. § 348(c)(3) (emphasis added).

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[2] Petitioner argues further that the Ninth Circuit's decision somehow conflicts with the D.C. Circuit's decision in *Public Citizen*, which held that the virtually identical color additive Delaney clause does not permit a *de minimis* exception, and which did *not* adjudicate the food additive issue resolved by the Ninth Circuit here. Petitioner's argument rests on the proposition that the *Public Citizen* opinion counselled the Ninth Circuit to consider the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq.—which contains a lower standard for the licensing of carcinogenic pesticides—in determining whether there is a *de minimis* exception under § 409 of the FFDCA, a wholly separate Act. *Public Citizen* contains no such suggestion. FIFRA—which NACA describes as "the principal pesticide regulatory statute" (Pet. at 19 (emphasis omitted))—is, moreover, merely the threshold licensing scheme for all pesticides—including rat poison, weed killers and lawn chemicals—regardless of whether the pesticide is used in food products. FIFRA includes no directive, either explicit or implicit, that substances that are licensable under its standard should be exempt from other regulatory schemes, and makes absolutely *no* attempt itself to set safe or appropriate levels of pesticide residues in food.

This unequivocal command—and more unequivocal language is difficult to imagine—is underscored by the overall statutory structure. Section 409 sets out the general safety standard that no regulation permitting use of a food additive shall issue

> if a fair evaluation of the data before the Secretary . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, that *no additive shall be deemed to be safe* if it is found to induce cancer . . . . [21 U.S.C. § 348(c)(3) (emphasis added)]

In evaluating the data for risks other than cancer, the agency is directed to consider "the probable consumption of the additive," "the cumulative effect of such additive in the diet," and other appropriate "safety factors." *Id.* § 348(c)(5). The Delaney clause, however, stands in stark contrast to this general "evaluation of the data . . . under the conditions of use" scheme. *Id.* § 348(c)(3). The Delaney clause, as we have stressed, mandates that once a substance is found to induce cancer, a determination of safety based on probable consumption or cumulative effect cannot suffice.[3]

The legislative history of section 409 is equally unequivocal and confirms the congressional intent that the

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[3] NACA complains that the Ninth Circuit "unjustifiably cited *Public Citizen* . . . as authority for rejection of EPA's *de minimis* interpretation of the food additive Delaney clause." Pet. at 18; *see also id.* at 21 (referring to the court's "misplac[ed] reliance on *Public Citizen*'s color additive findings . . . ."). But, the Ninth Circuit cited *Public Citizen* only to demonstrate that "its reasoning with respect to the *language of the statute* is equally applicable to both Delaney clauses." Pet. App. 7a (emphasis added). And, EPA agrees that "[t]here are no significant differences in the wording of the food additives and color additives Delaney clauses" and thus that "[t]he precise language of the food additives Delaney clause suggests congressional rigidity . . . ." Final Order, Pet. App. 85a.

Delaney clause be construed according to its terms. As the Ninth Circuit explained:

> The food additive Delaney clause was enacted in response to increasing public concern about cancer. It was initially part of a bill, introduced . . . by Congressman Delaney . . . . The bill, intended to ensure that no carcinogens, no matter how small the amount, would be introduced into food, was at least in part a response to a decision by the FDA to allow a known carcinogen, the pesticide Aramite, as an approved food additive . . . . Of the FDA's approval for sale of foods containing small quantities of Aramite, Congressman Delaney stated:
>
> > The part that chemical additives play in the cancer picture may not yet be completely understood, but enough is known to put us on our guard. . . . The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anti-carcinogen provision.
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> . . . . The scientific witnesses who testified before Congress [also] stressed that because current scientific techniques could not determine a safe level for carcinogens, all carcinogens should be prohibited. [Pet. App. at 8a-9a (citations omitted).] [4]

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[4] NACA's suggestion that EPA's "new and changed interpretation," offered thirty years after the statute was enacted, should carry greater weight than the contemporaneous construction by the agency initially charged with interpreting the statute turns the applicable principles upside down. It is the Ninth Circuit that put things in their proper order:

> Throughout its 30-year history, the Delaney clause has been interpreted as an absolute bar to all carcinogenic food additives. In 1958, the Department of Health, Education, and Welfare (which would be charged with administering the food additive provisions of the newly enacted Delaney clause) interpreted the clause as removing all agency discretion regarding car-

To be sure, petitioner, while conceding that the "meaning of the Delaney clause may be clear with respect to non-pesticide food additives regulated exclusively under FFDCA," argues that a different rule should apply to pesticide food additives. Pet. at 24. This argument is flatly wrong.

As a threshold matter, section 409 itself does not differentiate between types of food additives, stating simply that "*no* additive shall be deemed to be safe if it is found to induce cancer. . . ." 21 U.S.C. § 348(c)(3) (emphasis added). Thus, NACA's argument must reduce to the contention that Congress either did not intend for pesticide residues that concentrate in processed foods to be treated as food additives, or that Congress intended

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> cinogens. As a contemporaneous agency construction of the statute, this interpretation is entitled to great weight. *See Norwegian Nitrogen Products Co. v. United States*, 288 U.S. 294, 315 (1933). [Pet. App. at 9a (citations to the Final Order and legislative history omitted).]

NACA's objection that this contemporaneous agency construction was made by HEW rather than EPA (*see* Pet. at 25), ignores the undisputed fact that when the Delaney clause was enacted, HEW was the agency charged with administering the FFDCA for all foods, including those containing pesticides, and moreover, that EPA also agreed with this construction from 1970, when EPA was created, until the Agency's abrupt change in October, 1988.

Indeed, as the Ninth Circuit found further,

> Congress has repeatedly ratified a strict interpretation of the Delaney clause by reenacting all three FFDCA provisions which contain Delaney clauses without changing the Agency's interpretation. *See* 21 U.S.C. § 348 (amended 1960, 1962, 1984); 21 U.S.C. § 360b (amended 1988, 1991); 21 U.S.C. § 376 (amended 1960, 1962, 1970, 1976). [Pet. App. at 9a]

As this Court has stated, "[w]hen the statute giving rise to the longstanding interpretation has been reenacted without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *Federal Deposit Ins. Corp. v. Philadelphia Gear Corp.*, 476 U.S. 426, 437 (1986) (quotation omitted).

that the identical language of section 409 be construed differently for pesticide food additives than for other food additives. Neither of these contentions can withstand a moment's scrutiny.

First, there can be no real dispute that section 409, which includes the food additive Delaney clause, does in fact apply to pesticide residues that concentrate in processed foods. As EPA acknowledged:

> [t]he case of *United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975), held that a pesticide chemical in a processed food was a "food additive" regulated by section 409 and this decision is well-supported by the language of the statute and the legislative history on the issue. [Final Order, Pet. App. at 65a-66a.] [5]

Second, petitioner's assumption that because *section 408* contains standards for pesticides in *raw foods*, Congress must also have meant for those same standards to be used under section 409 for regulating pesticides that concentrate in processed foods is directly contradicted by explicit statutory language which mandates the exact relationship between sections 408 and 409.[6] As the Ninth Circuit pointed out:

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[5] Indeed, as the Ninth Circuit pointed out:

> [The] contention that Congress never intended the food additive provision to encompass pesticide residues is belied by the events prompting passage of the provision into law: FDA approval of Aramite was the principal impetus for the food additive Delaney clause and Aramite was itself a regulated pesticide. [Pet. App. at 10a.]

[6] Section 408 allows the agency to establish tolerances or exemptions for certain uses of pesticides on raw agricultural products if such regulations would "protect the public health." 21 U.S.C. § 346a(b). Unlike section 409, section 408 does not contain Delaney clause language explicitly precluding a finding of safety if the substance induces cancer and moreover, also allows the agency to

> [S]ection 402 of the FFDCA, 21 U.S.C. § 342(a)(2)(C), [the "flow-through" provision] expressly harmonizes [section 408] with the Delaney clause by providing that residues on processed foods may not exceed the tolerance level established for the raw food. The statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409. [Pet. App. 7a-8a; *see also id.* at 4a-5a.]

In sum, NACA's elaborate statutory claim comes down to petitioner "in effect ask[ing the courts] to approve what [EPA] deems to be a more enlightened system than that which Congress established." Pet. App. at 11a. As the Ninth Circuit said in rejecting that re-

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consider the "necessity for the production of an adequate, wholesome, and economical food supply." *Id.* In enacting section 408, Congress did not intend to affect regulation of pesticides in processed foods:

> It is intended . . . to draw a sharp line of distinction between the subjects covered by this bill and the subjects which are unaffected by it. This bill covers the regulation of the residue from pesticide chemicals which may remain in or on food in its raw or natural state as usually purchased by the consumer or the food processor. . . . *This bill does not attempt to regulate the residue from pesticide chemicals which may remain in or on processed, fabricated, or manufactured food other than by limiting the permissible residues on raw agricultural commodities. Food processed by operations such as cooking, freezing, dehydration, or milling would remain subject to [other sections of the FFDCA] rather than being regulated by this bill.* For example, the provisions of this bill would apply to the residue of DDT remaining in or on fresh apples or apples which are washed or waxed for market. The provisions of this bill would not apply to any residue of DDT remaining in or on applejuice or applesauce which may be prepared or produced from such apples. [H.R. Rep. No. 1385, 83rd Cong., 2d Sess. 6-7 (1954), XII *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* 838-39 (1979)]

quest, "Revising the existing statutory scheme, however, is neither our function nor the function of the EPA." *Id.*

CONCLUSION

For the reasons stated above, the Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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